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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

cánts: LINSLEY et al.

Serial No.: 07/722,101

Filed: June 27, 1991

Title: LIGAND FOR CD28

RECEPTOR ON B CELLS

AND METHODS

Examiner: D. ADAMS

Group Art Unit: 180



## RESPONSE TO RESTRICTION REQUIREMENT

Hon. Commissioner of Patents and Trademarks Washington, D.C. 20231

Sir:

This response is in reply to the restriction requirement contained in the Office Action dated November 27, 1991 (Paper No. 5).

The Examiner has required a restriction under 35 U.S.C. § 121 to one of the following inventions:

Group I: Claims 1-62, drawn to a method for regulating T-cell responses by contacting CD28 positive T cells with a ligand for CD28 receptor, Classified in Class 424, subclasses 85.8 and 88; and a monoclonal antibody reactive with a fusion protein (claims 25 and 43); and CD28Ig fusion protein (claim 33); and a method for inhibiting functional T cell responses (claim 35); and a method for regulating the level of cytokines in vivo (claim 45); and a method for treating immune system diseases (claim 52); and a method for treating cancer (claim 59);

Group II: Claims 63-66, drawn to a method of treating T cell proliferation in graft vs. host disease with a ligand for CD28 receptor and an immunosuppressant, classified in Class 424, subclasses 85.8 and 88, and 85.1, and Class 514, subclass 200+; and

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Group III: Claims 67-76; drawn to an assay method to detect a ligand reactive with target receptor, classified in Class 436, subclasses 63 and 501. (The Examiner listed the claims in this Group as "67-75", but applicants assume that the Examiner intended to include claim 76 in this Group).

#### **ELECTION**

As required, applicants elect with traverse to prosecute the claims of Group I, claims 1-62, in the present application. Applicants understand that claims 63-76 will be withdrawn from further consideration by the Examiner under 37 C.F.R. § 1.142(b) as being directed to a non-elected invention. Applicants reserve the right to prosecute these withdrawn claims in subsequently-filed applications.

### TRAVERSAL

Applicants traverse the restriction requirement for the following reasons. The basis advanced by the Office for restriction of Groups I-III (the Examiner refers to Groups II-IV in the Restriction Requirement, however, applicants assume the Examiner meant to refer to Groups I-III) is that the inventions are "distinct methods of use" and differ "with respect to their process steps, and ingredients as well as presenting different issues of enablement and patentability". However, applicants note that the claims of Group II, claims 63-66, are directed to a method that involves the regulation of T cell responses (in this case, inhibiting T cell proliferation) to accomplish the treatment of graft versus host disease by contacting T cells with a ligand for CD28 receptor (claim 63). Additionally, the method of claims 63-66 uses an immunosuppressant. Similarly, the claims of Group I are directed to methods involving the regulation of T cell responses by contacting T cells with a ligand for CD28 receptor (claim 1). Therefore, the method recited in the claims

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of Group II is carried out using the ligand for CD28 receptor which is the subject of the claims of Group I. The method recited in claim 63 provides a specific embodiment of the invention disclosed in the application and recited in claim 1. The art with respect to the method recited in the claims of Group I and the method in the claims of Group II overlaps, and therefore separate searches are not required. Applicants note that the claims of both Groups I and II are classified in Class 424. Therefore, the burden on the Office to search and examine the claims of these groups together is much less than that placed on applicants to prosecute the claims in separate applications. Separate prosecution of the claims of Group I and Group II would result in a needless duplication of effort and waste of resources for both applicants and the Patent Office.

With respect to the claims of Group III, the assay method which is the subject matter of these claims relies on the ability of a ligand for a target receptor to be recognized by the target receptor. This ability is inherent in the ability of the ligand for CD28 receptor to recognize the CD28 receptor on T cells, as recited in claim 1. Search of the claims of Group III will necessarily overlap with search of the claims of Groups I and II. Therefore, the burden on the Office to search and examine these claims together in a single application is less than that placed on applicants to separately prosecute these Groups of claims.

For the record, with respect to the Examiner's comment that the secretary of the undersigned counsel for applicants, Ms. SaraLynn Mandel, said "it was her [Ms. Mandel's] policy to have restrictions mailed" (Restriction Requirement, page 2), counsel explains that in certain applications, for example where 1) there are a number of claims involved in an application and the Restriction Requirement; and 2) counsel believes it is advisable to discuss the Restriction Requirement and strategy for response

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with her client in view of the Examiner's written rationale for the Restriction, then, counsel will request that the Restriction Requirement be mailed. It is not counsel's "policy" to routinely refuse to make oral election on behalf of her clients, because counsel recognizes that such election, under the proper circumstances, will expedite prosecution. If the erroneous statement was communicated to the Examiner, then counsel regrets the misunderstanding and hopes that the above statement clarifies her intent in refusing to make the oral election.

#### CONCLUSION

In conclusion, applicants assert that the Restriction Requirement with respect to Groups I-III is improper, and urge the Examiner to reconsider and withdraw the Restriction Requirement and examine all of the claims together in a single application.

Respectfully submitted, LINSLEY et al.

Date: 12/27/91

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